



Exhibit 1

Claims Pending in Canadian Application Ser. No. 2,240,329

1. A dosage form for the oral administration of a methylphenidate drug, comprising two groups of particles, each containing said drug, wherein:
 - a) said first group of particles provides a substantially immediate dose of said drug upon ingestion by a mammal, and
 - b) said second group of particles comprises coated particles, said coated particles comprising from about 2% to about 75% by weight of said drug in admixture with one or more binders, said coating comprising a pharmaceutically acceptable ammonio methacrylate in a quantity sufficient to provide a dose of said medication delayed by from about 2 hours to about 7 hours following said ingestion.
2. The dosage form of claim 1 wherein said first group of particles comprises a pharmaceutically acceptable salt of methylphenidate in powder form.
3. The dosage form of claim 1 wherein said second group of particles comprises coated particles comprising a pharmaceutically acceptable salt of methylphenidate.
4. The dosage form of claim 2 wherein the amount of said pharmaceutically acceptable salt of methylphenidate in said first group of particles is from about 2% to about 99% by weight, based on the weight of said particles.
5. The dosage form of claim 4 wherein said pharmaceutically acceptable salt of methylphenidate comprises *dl-threo* methylphenidate hydrochloride.
6. The dosage form of claim 3 wherein said pharmaceutically acceptable salt of methylphenidate comprises *dl-threo* methylphenidate hydrochloride.
7. The dosage form of claim 1 wherein said second group of particles comprises from about 20 % by weight to about 50% by weight of filler, based on the total weight of the copolymer.

8. The dosage form of claim 7 wherein said filler is selected from the group consisting of talc, colloidal silica, fumed silica, gypsum, and glycerine monostearate.
9. The dosage form of claim 8 wherein said filler is talc.
10. The dosage form of claim 9 wherein the amount of talc is from about 35 % to about 45% by weight, based on the total weight of the copolymer.
11. The dosage form of claim 10 wherein the amount of talc is from about 38% to about 42% by weight, based on the total weight of the copolymer.
12. The dosage form of claim 11 wherein the amount of talc is about 40% by weight, based on the total weight of the copolymer.
13. The dosage form of claim 1 wherein the ammonio methacrylate copolymer comprises acrylic groups and quaternary ammonium groups in a ratio of from about 10:1 to about 50:1.
14. The dosage form of claim 13 wherein said ratio is from about 15:1 to about 45:1.
15. The dosage form of claim 14 wherein said ratio is from about 15:1 to about 20:1.
16. The dosage form of claim 15 wherein said ratio is from about 30:1 to about 40:1.
17. The dosage form of claim 1 comprising a first ammonio methacrylate copolymer comprising, as polymerized units, acrylic groups and trimethylammonioethyl methacrylate in a ratio of from about 30:1 to about 40:1, and a second ammonio methacrylate copolymer comprising, as polymerized units, acrylic groups and trimethylammonioethyl methacrylate in a ratio of from about 15:1 to about 20:1
18. The dosage form of claim 17 wherein the ratio of said first copolymer to said second copolymer is from about 90:10 to about 99:1.
19. The dosage form of claim 18 wherein the ratio of said first copolymer to said second copolymer is from about 93:7 to about 97:3.

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20. The dosage form of claim 19 wherein the ratio of said first copolymer to said second copolymer is about 95:5.
21. The dosage form of claim 1 wherein said delay is from about 3 hours to about 6 hours.
22. The dosage form of claim 1 wherein said delay is from about 4 hours to about 5 hours.
23. A dosage form for once-daily oral administration of a methylphenidate drug comprising:
 - a) particles comprising from about 2% by weight to about 99% by weight of said methylphenidate drug, in admixture with one or more binders,
 - b) a coating exterior to said methylphenidate drug, comprising an ammonio methacrylate copolymer in a quantity sufficient to provide a dose of said methylphenidate delayed by from about 2 hours to about 7 hours following administration, and
 - c) on the exterior surface of said coating, a layer comprising said methylphenidate drug, to provide a substantially immediate dose of said methylphenidate upon administration.
24. The dosage form of claim 23 wherein said methylphenidate is *dl-threo*-methylphenidate hydrochloride.
25. The dosage form of claim 23 wherein said methylphenidate is *d-threo*-methylphenidate hydrochloride.
26. The dosage form of claim 23 wherein said coating comprises a first ammonio methacrylate copolymer comprising, as polymerized units, acrylic groups and trimethylammonioethyl methacrylate in a ratio of from about 30:1 to about 40:1, and a second ammonio methacrylate copolymer comprising, as polymerized units, acrylic groups and trimethylammonioethyl methacrylate in a ratio of from about 15:1 to about 20:1.
27. A dosage form for the oral administration of *d-threo*-methylphenidate hydrochloride comprising two groups of particles, each containing *d-threo*-methylphenidate, wherein:

a) said first group of particles comprises *d-threo*-methylphenidate hydrochloride and provides a substantially immediate dose of said *d-threo* methylphenidate upon ingestion by a mammal, and

b) said second group of particles comprises coated particles, said coated particles comprising from about 2% to about 75% by weight of *d-threo*-methylphenidate hydrochloride in admixture with one or more binders, said coating comprising a pharmaceutically acceptable ammonio methacrylate copolymer in an amount sufficient to provide a dose of said *d-threo*-methylphenidate delayed by from about 2 hours to about 7 hours following said ingestion.

28. A dosage form of a pharmaceutically acceptable salt of *d-threo*-methylphenidate providing an *in vitro* release profile comprising two pulses of drug release, wherein said pulses are temporally separated by from about 2 hours to about 7 hours.

29. A dosage form of a pharmaceutically acceptable salt of *d-threo*-methylphenidate providing an *in vivo* plasma concentration of said *d-threo*-methylphenidate comprising two maxima, wherein said maxima are temporally separated by from about 2 hours to about 7 hours, and wherein the magnitude of said maxima differ by no more than about 30 percent.

30. A dosage form according to claim 23 wherein said ammonio methacrylate copolymer comprises a first copolymer of methyl methacrylate, ethyl acrylate and TAMCl in a ratio of 2:1:0.1 and a second copolymer of methyl methacrylate, ethyl acrylate, and TAMCl in a ratio of 2:1:0.2.

31. A method for treating disease in a patient in need of treatment comprising administering to the patient a dosage form providing once-daily oral administration of *d-threo*-methylphenidate hydrochloride, said dosage form comprising two groups of particles, each containing *d-threo*-methylphenidate, wherein:

a) said first group of particles comprises from about 2% to about 99% by weight of *d-threo*-methylphenidate hydrochloride and provides a substantially immediate dose of said *d-threo* methylphenidate upon ingestion by a mammal; and

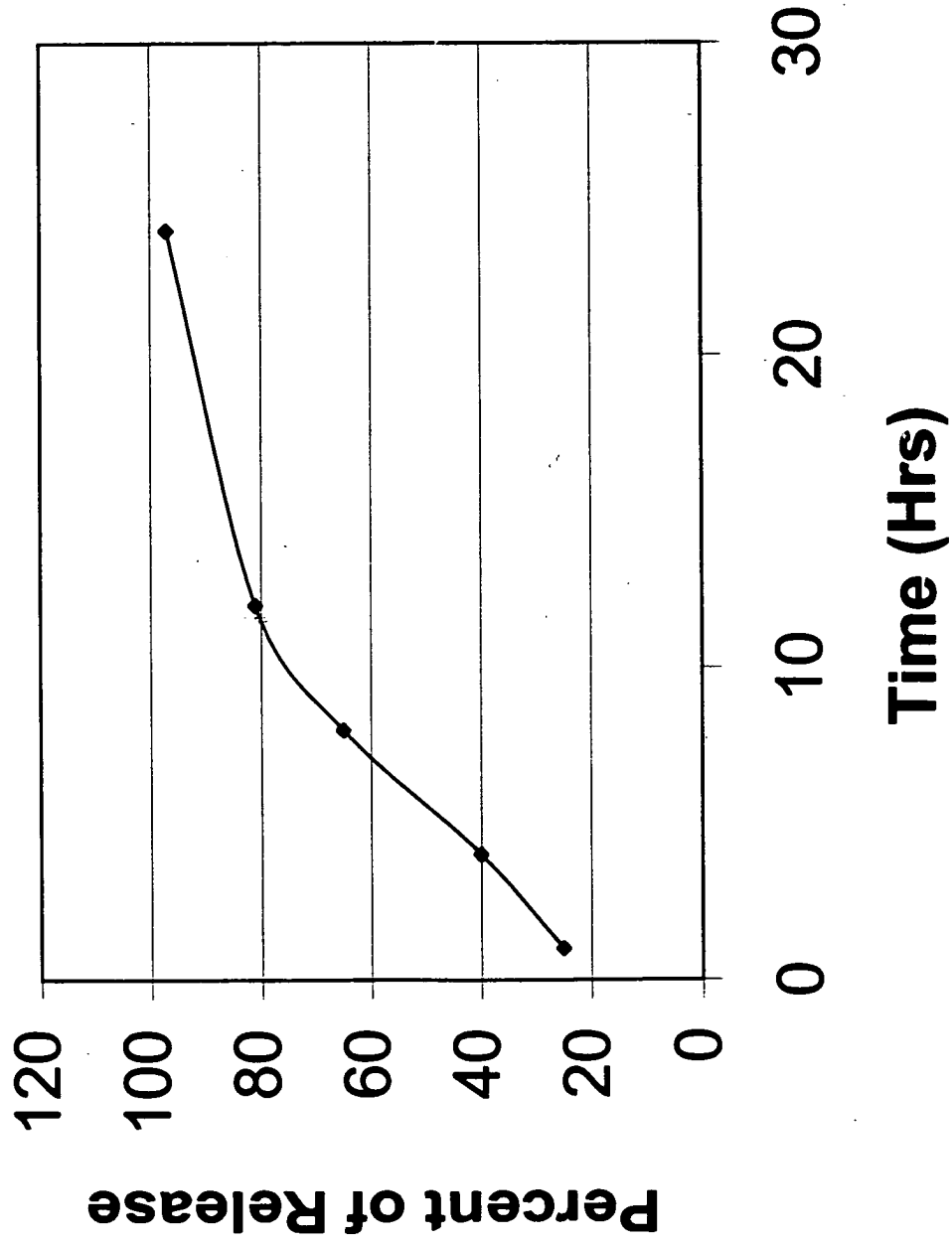
b) said second group of particles comprises coated particles, said coated particles comprising from about 2% to about 75% by weight of *d-threo*-methylphenidate in admixture with one or more binders, and a coating consisting of an ammonio methacrylate copolymer in

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an amount sufficient to provide a dose of said *d-threo*-methylphenidate hydrochloride delayed by from about 4 hours to about 7 hours following said ingestion.

32. A dosage form of a pharmaceutically acceptable salt of *a* methylphenidate providing an *in vitro* release profile comprising two pulses of drug release, wherein said pulses are temporally separated by from about two hours to about seven hours.
33. A dosage form of a pharmaceutically acceptable salt of *a* methylphenidate providing an *in vivo* plasma concentration of said methylphenidate comprising two maxima, wherein said maxima are temporally separated by from about two hours to about seven hours and wherein the magnitude of said maxima differ by no more than about 30 percent.

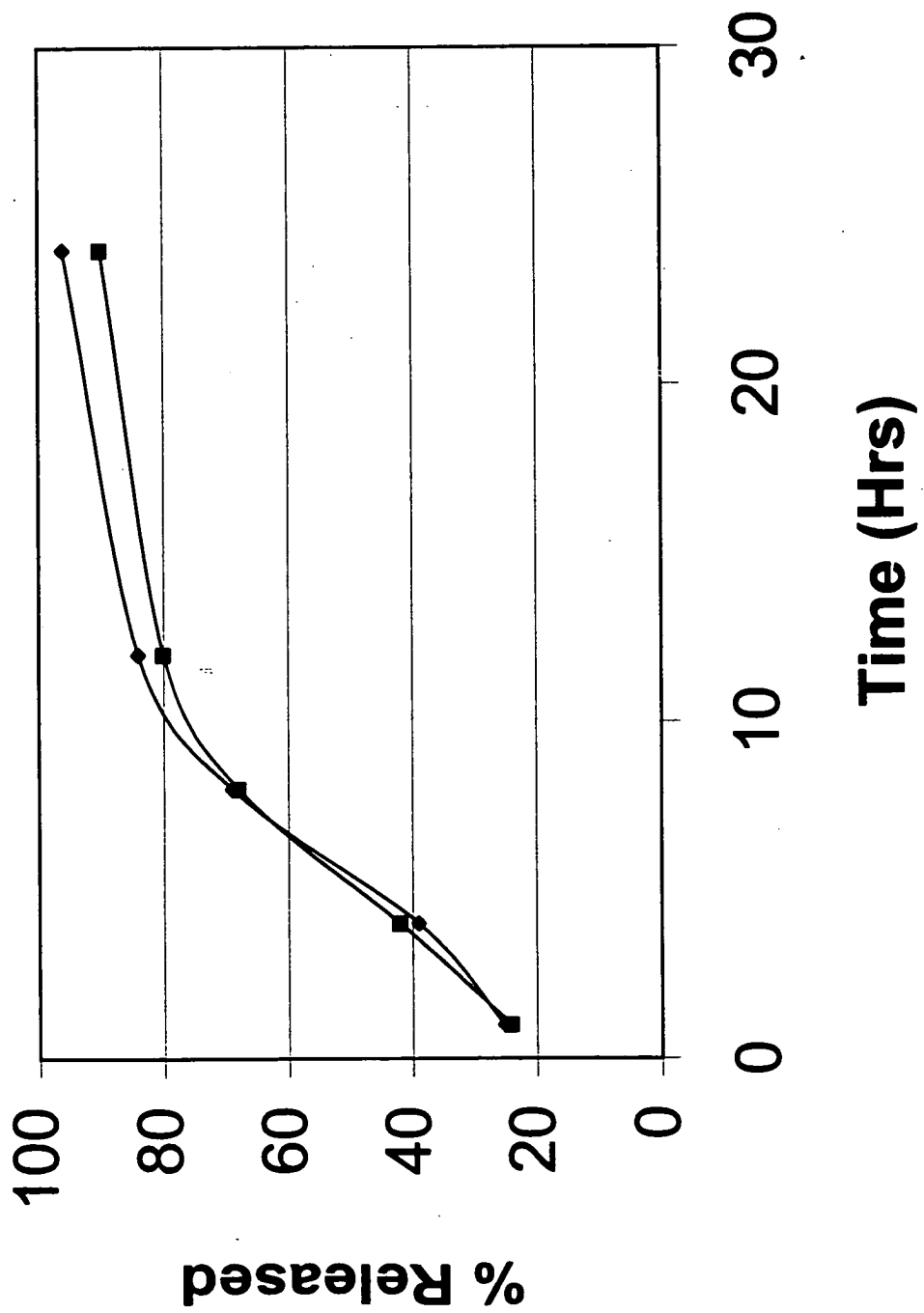
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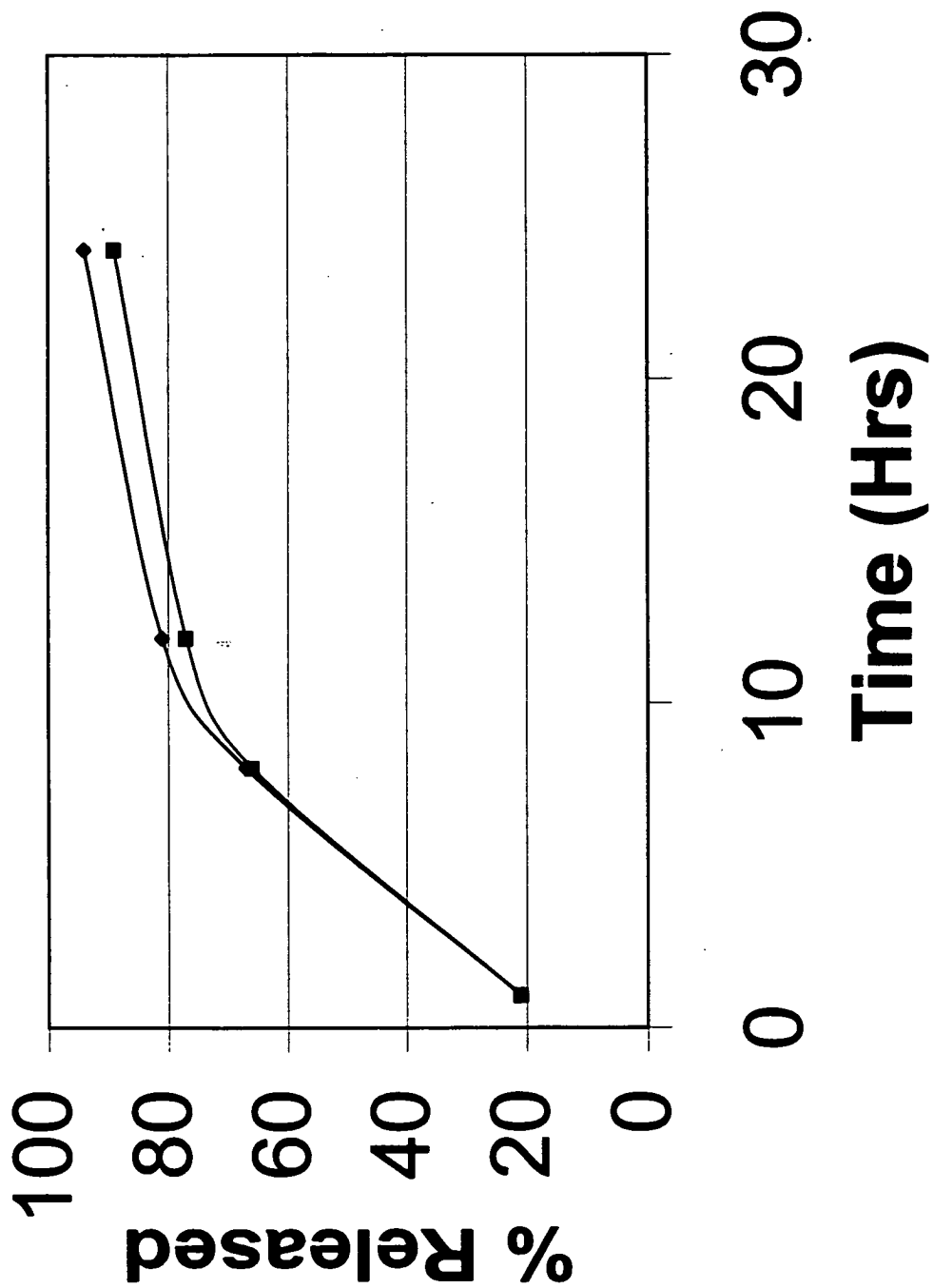
◆ Pseudoephedrine

Exhibit 2

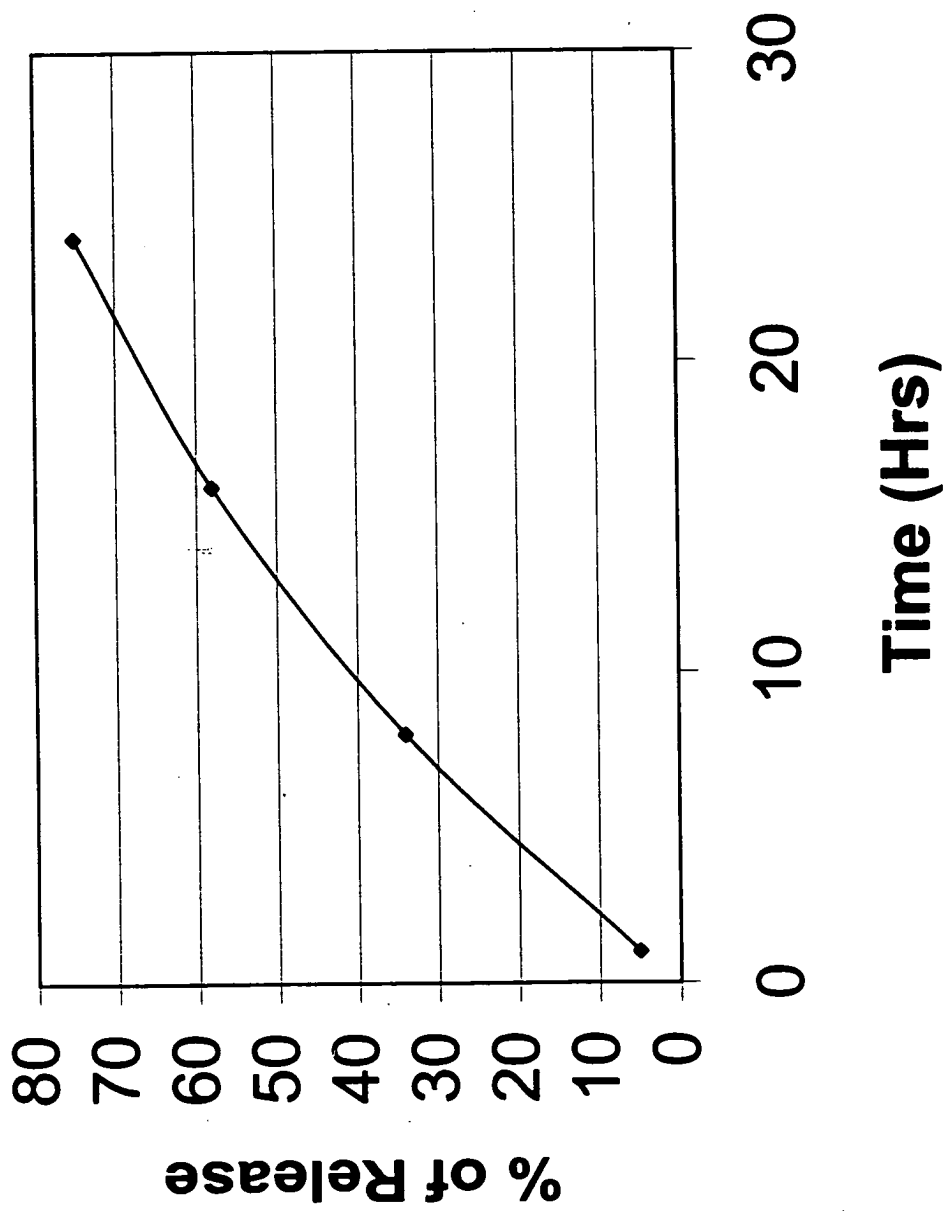
974 Patent Example 2



974 Patent Example 3

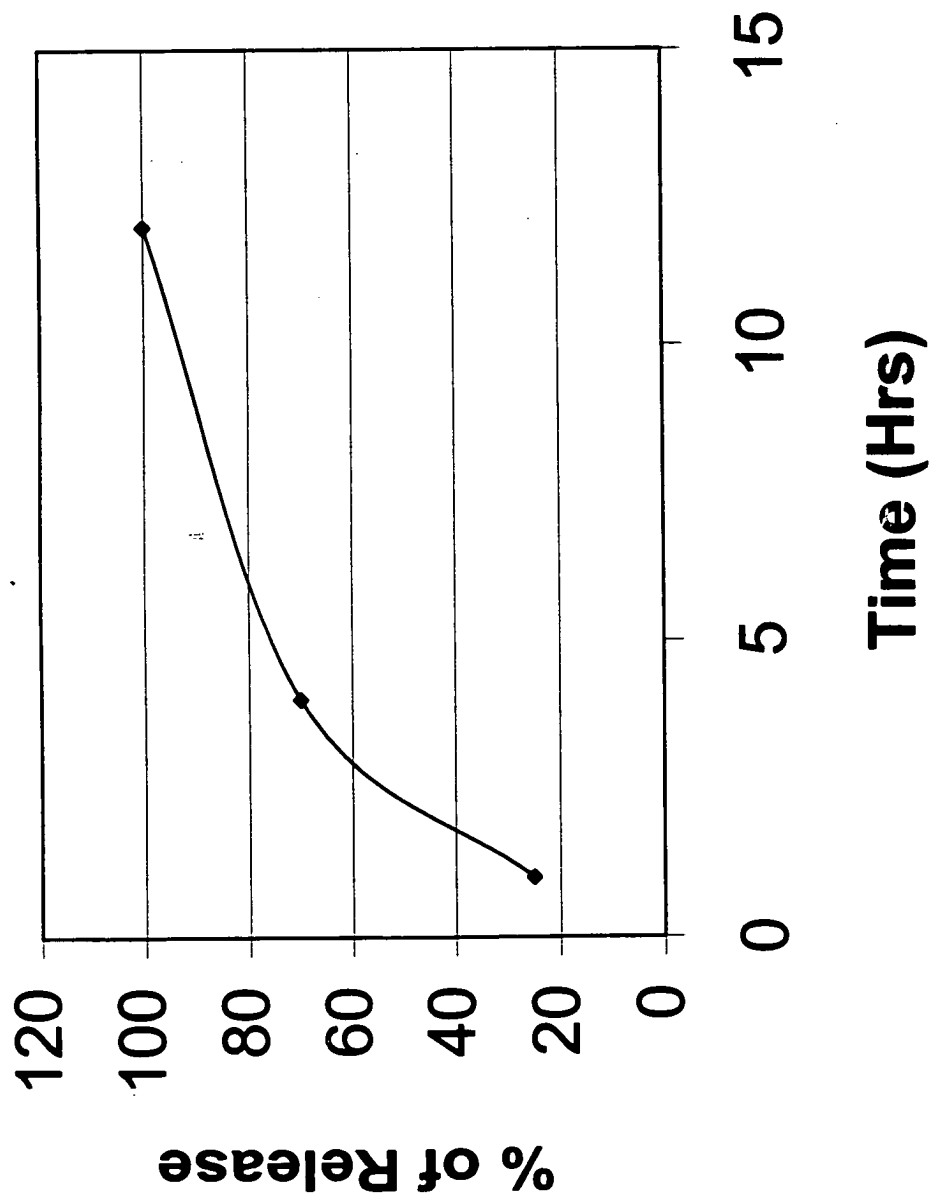


974 Patent Example 4



—♦— Potassium Chloride

974 Patent Example 5



—◆— Potassium Chloride